

SPL ER/DL Team

May 9, 2012

Minutes

Chair: Pat Cowall

Teleconference information:

USA Toll-Free 866-213-2145

Access code: 273 8216

Agenda:

Presentation by Yoshi Tokiwa, FDA

There was no time for other agenda items. The following will be carried over for discussion to the next meeting.

Other discussion topics to carry over until the next meeting:

1. SPL Downloadable Data and Inner Packs:

- Inner NDCs now displayed in description field of NDC directory:
- Download available on SPL Resources page.

2. Continued discussion from March 28 teleconference: Including inner NDC codes in SPL Data -- when both the inner and outer packaging contain the same NDC code (eg vial in an outer carton):

Beverly Haslip: We recently received a SPL validation error from **CBER** for a **One-count carton finished pack** where originally the carton and inner syringe NDC were the same. CBER requested/required that a different NDC be used for each level of packaging. Historically for this type of packaging configuration, for both CBER and CDER products, our company has used the same NDC for both the carton and the inner product. Lonnie has previously indicated that for **CDER** products, the elist system expects different NDC's for a pack where there is multilevel packing (different types of packaging); however, at this time CDER has not implemented this validation rule. We wanted to get the groups' perspective about the application of this rule to CDER products, and see if anybody was implementing or is in the process of evaluating the use of two different NDC pack codes:.

- for a One-count finished pack e.g., one vial contained within a carton
- Multi-count carton e.g., 10 vials contained within a carton

3. New document type: Establishment de-registration

- How to remove unused site from an existing file. Submit the new file – it will override the old file.
- How to merge a company into
 - submit an “out of Business” for newly merged company
 - add the new company to the new parent company.

4. Kathy Lins: We manufacture a product for a PLD. The PLD owns the application and labeling. Hospira has been asked to drug list our own NDC Number as the manufacturer.

Meeting note: this has been resolved.

5. Mary Beth Kline: Drug listing a foreign label – will the FDA accept foreign labels? We need to drug list an API for one of our foreign establishments (we are their US agent) that is being exported into the US. However, their label is in German. Is this acceptable with the FDA? Has anyone else encountered this?

6. When discussing how Dun & Bradstreet might have some 'inconsistent' address information with that of the actual site, Lonnie mentioned that an override can be requested if it fails at validation because of the address checking. He also noted that for overrides, the core id must be specified in the e-mail request.

7. Updates from SPL Leadership Team – to be discussed at our next meeting

a. Usage of terms and UNII in SPL files. (L Smith)

- Note: using a substance correctly.
- Example: banana as a substance or as an artificial flavor. (This data is used by RxNorm to determine potential allergic reactions, etc)

b. Downstream use of SPL data by FDA safety evaluators. (L Smith)

- They would like to use the SPL data for their adverse event reporting.
- Rx and OTC
- A lot of people are very interested in the SPL data. SPL available on Daily Med and in FDA systems. Safety evaluators will send list to Lonnie.
 - Basis of strength.
- FDA is very interested in having SPL viewed in a positive light – taking a lot of effort to create the SPL...so the data should be right.

8. Walk ins: Bring any other topics to the meeting.

a. Howard: Has anyone heard about the submission of sales samples being done via XML? ACA 6004

9. Next meeting – May23, 2012. Discuss upcoming CDER validation rule that “links” establishments to NDC product codes.

If you want to see how the SPL will look with this new information, go to the following label on the FDA Online Repository, scrolling down to the establishment data at the very end of the file:

<http://www.accessdata.fda.gov/spl/data/8ee1cd0e-bad7-48ff-9e25-8710edb812ec/8ee1cd0e-bad7-48ff-9e25-8710edb812ec.xml>.

The label is also available on the DailyMed but the stylesheet on that site does not appropriately display the information. (<http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?ndc=63459-548-28&start=1&labeltype=all>)